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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/766,912

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Carl Ernest Alexander

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466 7590 12/14/2011  
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EXAMINER

ROBERTS, LEZAH

ART UNIT

PAPER NUMBER

1612

NOTIFICATION DATE

DELIVERY MODE

12/14/2011

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	Application No.	Applicant(s)
	10/766,912	ALEXANDER ET AL.
	Examiner	Art Unit
	LEZAH ROBERTS	1612

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 25 November 2011 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on November 25, 2011. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
- NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.

6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1, 3, 4, 7, 8, 10, 11, 13, 18, 23-29, 31, 35 and 36.

Claim(s) withdrawn from consideration: 10, 11, 18, 29 and 31.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.

12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_

13. ☐ Other: \_\_\_\_\_.

/Lezah W Roberts/  
Primary Examiner, Art Unit 1612

Continuation of 11. does NOT place the application in condition for allowance because:

In regard to the Obvious Double Patenting Rejection, MPEP 804 B1 states:

If a 'provisional' nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer.

Since the instant situation does fit this exception, the rejection is maintained.

In regard to the New Matter rejection, the claims recite "between 32% to 35% water". Although one example has 32.1%, this does not support the range "between 32% and 35%" because this range also includes values below 32.1 such as 32.01%, which is not supported by the instant specification. Therefore although Example 5 discloses 32.1, this does not support "32.01%" or even "32.05%", which are encompassed by "between 32% to 35%". Further there appears to be no support for 35% or values slightly below 35% (34.9%) water with regard to a composition comprising agar. Example 8 does not appear to support the upper limit. Example 8 comprises 34.45% water and therefore does not support 34.9%, a value between 32% and 35%, nor does it support 35%. In regard to the range "between 13.9% and 43%", this range includes 42.99% and 14%, which do not appear to be disclosed by the instant specification. The instant specification also does not appear to disclose 13.9% or 43% nor does it support all values included in the range "between 13.9% and 43%" with regard to agar. In regard to Example 6, the example comprises 13.9% water with regard to gelatin and not agar. When agar, which is recited in the instant claims, is used, 17.3% water is used. It is also noted that the claim recites the limitation "between 13.9% and 43%" and not "from 13.9% to 43%" and therefore would not appear to include "13.9%". Therefore the claim does not encompass "13.9%", when agar is the gelling agent in the composition. In regards to Example 7, agar is not used in this example and therefore the limitation appears to be New Matter in regard to agar. Therefore the rejection is maintained.

In regard to the Obviousness Rejection over Bolton and the content of water, a product encompasses a composition and at a certain point in the drying process, the composition of Bolton comprises the water content recited in the instant claims because the water content goes from 45%, above the recited range, to 4.6%, below the recited range. Therefore one of ordinary skill in the art would reasonably conclude that a composition with a water content recited by Applicant is made. Even if this was not the case, the claims of Bolton recite the composition comprises "gelling agent, 0.5 to 4%; oil, 10 to 20%; therapeutic agent, 50 to 75%; [and] the balance water". Therefore water may comprise 1% to 39.5% water based on the percentages of the other components. The prior art does not disclose the exact claimed values of between 32% to 35% water as recited in claim 1 and between 13.9% and 43.1% water recited in claim 23 but does overlap disclosing 1% to 39.5%: in such instances even a slight overlap in range establishes a prima facie case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Therefore the amount of water in the claims is obvious over the amount disclosed by the reference. Therefore given that the compositions of Bolton include those compositions comprising 0.5 to 4% agar and 1% to 39.5% water, one of ordinary skill in the art would reasonably conclude that these compositions would produce semi-solid products and not only slurries or brittle compositions, and would also teach a water content of above 4.6%. Thus Bolton does not teach away from the semi-solid compositions claimed in the independent claims. Further water determines the structure of the compositions because its content determines whether the compositions are slurries or rigid structures. As pointed out in MPEP 2144.05 IIB, only result effective variables can be optimized. A particular parameter must first be recognized as a result effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or multiple ranges of said variable may be characterized as routine experimentation. In re Antoine, 195 USPQ 6 (CCPA 1977). Therefore it would have been in the relative skill of one of ordinary skill in the art to have adjusted the water content to obtain a tablet with the desired gel structure. Further Bolton does not appear to disclose slurries, as asserted by Applicant, but discloses the compositions form molded gel tablets, and then the molded tablets are dried to reduce water content (col. 4, lines 49-52). This implies that the compositions were semi-solid structures before drying and not slurries. It is also noted the compositions are "gel" tablets and may comprise 1 to 39.5% water and therefore the reference encompasses semi-solid gels and not only hard gels as asserted by Applicant. Thus Bolton does not teach away from the compositions of the instant claims.

In regard to Athanikar, it was used as evidence to support antibiotics are used in oral compositions and not as a secondary reference to modify the teachings of Bolton. Thus Applicant's arguments in regard to Athanikar are not persuasive.

In regard to Huang, the water content is taught by Bolton. Further instant claim 23 recites a water content of 13.9% and 43.1%, which overlaps that disclosed by Huang, 1 to 20%. Therefore the water content of Huang is not far less than the presently claimed range. Therefore the rejections are maintained.

In regards to rejoinder, the claims are not allowable and therefore the withdrawn claims are not rejoined.